IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
NORTHERN DIVISION

BILLY RAY KENDRICK, Husband
AND NITA KENDRICK, Wife **PLAINTIFFS**

v. **Case No: 3:19-cv-00014-LPR**

WRIGHT MEDICAL TECHNOLOGY, INC.
AND JOHN DOES, Nos. 1–5 **DEFENDANTS**

ORDER

Pending before the Court is a Motion for Summary Judgment by Defendant Wright Medical Technology, Inc.[1] Plaintiffs Billy Ray Kendrick and Nita Kendrick sued Wright under theories of negligence, strict liability, and breach of warranty.[2] Plaintiffs' claims center around a Wright-manufactured knee replacement device that was implanted into Mr. Kendrick and subsequently failed.[3] Wright moves for summary judgment on all claims.[4] For the reasons discussed below, the Court grants Wright's Motion.

I. Background[5]

Viewed in the light most favorable to Mr. Kendrick, the record reveals the following. Wright received FDA clearance for a total knee arthroplasty system branded as the Evolution Medial-Pivot Knee System (hereinafter called the "Knee System") in 2010 and began marketing

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1 Def.'s Mot. for Summ. J. (Doc. 28).

2 Pls.' Compl. (Doc. 2) ¶¶ 12, 15; Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 13. Plaintiffs brought suit in the Circuit Court for the Chicksawba District, Mississippi County, Arkansas. Pls.' Compl. (Doc. 2). Wright removed the suit to this Court pursuant to 28 U.S.C. § 1332. Def.'s Notice of Removal (Doc. 1). Ms. Kendrick has a claim for loss of consortium. Her claim is derivative of Mr. Kendrick's claims.

3 Pls.' Compl. (Doc. 2) ¶¶11–17.

4 Def.'s Mot. for Summ. J. (Doc. 28) at 2–3.

5 On summary judgment, the Court recites the genuinely disputed facts in a light most favorable to the Plaintiffs, including giving the Plaintiffs all reasonable inferences from the facts. The Court considers the most pro-plaintiff version of the record that a rational juror could conclude occurred. Accordingly, the Court's factual recitation is only good for the summary judgment motion.

it that same year.[6] Wright manufactured the Knee System.[7] The Knee System is a prescription orthopedic joint prosthesis used for total knee replacement surgeries.[8] The Knee System comprises femoral, tibial, and patellar components as well as a tibial insert.[9] Implantation of the Knee System involves the use of cement.[10]

In the ten years the Knee System has been in use, Wright is aware of only two instances when femoral components of the Knee System fractured postoperatively.[11] Mr. Kendrick's lawsuit involves one of the two instances.[12] According to Wright, two femoral component failures equates to an incidence rate of approximately 0.003%.[13] Mr. Kendrick has not identified any other instances of failure of the Knee System.

The specific Knee System at issue here was manufactured in 2010.[14] On September 21, 2011, Mr. Kendrick underwent a knee replacement surgery.[15] During the surgery, Mr. Kendrick's orthopedic surgeon, Dr. Ball, implanted the Knee System into Mr. Kendrick's right leg.[16] Approximately four years later, Mr. Kendrick began experiencing pain in his right knee.[17] As a result, medical providers X-rayed Mr. Kendrick's right knee.[18] Dr. Ball reviewed the X-rays,

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6 Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 3.

7 *Id.* ¶ 1.

8 *Id.* ¶ 1.

9 *Id.* ¶ 2.

10 *Id.*

11 *Id.* ¶ 5. "In 2013, Wright sold the division of its orthopedic implant manufacturing business responsible for the development and manufacture of the Knee System to MicroPort Scientific," which sells the Knee System to this day. *Id.* ¶ 4.

12 *Id.* ¶ 5.

13 *Id.*

14 *Id.* ¶ 6.

15 *Id.* ¶ 9.

16 *Id.* ¶¶ 1, 9.

17 Ex. 4 to Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37-4) at 90:5–13.

18 *Id.* at 90:14–18.

which revealed the presence of a metal foreign body in the joint space.[19] On September 23, 2015, Dr. Ball performed a revision (a "'redo' joint replacement") on Mr. Kendrick, at which time Dr. Ball explanted the Wright Knee System and implanted a system manufactured by another company.[20]

During the revision, Dr. Ball "noted that the femoral component [of the Knee System] had broken, and further noted there was osteolysis behind the femoral component, which he described as 'an absence of bone behind the flange.'"[21] Dr. Ball further "described the amount of bone loss as 'substantial … probably half an inch [in] thickness and an inch deep … [i]t was big … something you could stick your finger in.'"[22] Dr. Ball's testimony also revealed that the osteolysis behind the "femoral component would explain the breakage of the femoral component."[23] Finally, Dr. Ball testified that "this type of failure can occur without there being a defect in the product, and that 'this is exactly the sort of circumstance that could lead to a broken implant without a defect.'"[24]

Wright presents evidence from multiple experts. Jorge Ochoa, Ph.D, a failure analysis expert, inspected the explanted components of the Knee System and reported his findings to Wright.[25] Mr. Ochoa states that the inspected components "met all manufacturing specifications, and passed all quality and manufacturing control inspections before leaving Wright's control."[26]

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[19] *Id*.

[20] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 11. Ex. D to Mooney Decl. (Doc. 31) at 121.

[21] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 12.

[22] *Id.*

[23] *Id.*

[24] *Id.* Dr. Ball testified in his capacity as Mr. Kendrick's treating physician. Ex. 4 to Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37-4) at 13:24–14:18. As of the date of his deposition, Dr. Ball had only had one femoral component break: Mr. Kendrick's. *Id.* at 29:14–18.

[25] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 6. Plaintiffs have not questioned whether Dr. Ochoa is a qualified expert. Indeed, Plaintiffs have not raised any *Daubert* challenges with respect to any experts that Wright proffers in this litigation.

[26] *Id.*

Mr. Ochoa concluded that the subject Knee System components "were not designed or manufactured in a defective manner."[27] In addition to the expert report from Mr. Ochoa, Wright provided expert reports from Dr. Paul Edwards, an orthopedic surgeon, and Dr. David Feigal, an FDA and regulatory expert.[28] Wright's three expert opinions, "[t]aken in the aggregate, . . . opined that the subject Knee System did not contain any defect whatsoever."[29] Wright's experts also concluded that the "most likely cause of the breakage was osteolysis," which led "to [a] lack of support behind the femoral component [] and subsequent fatigue failure."[30]

Mr. Kendrick's expert, Dr. Carl McMillin, testified that he has not seen anything to indicate that the subject Knee System "was manufactured outside of the specification."[31] Dr. McMillin also admitted that, in his opinion, "there is no design defect with regard to the implant that was placed in Mr. Kendrick."[32] Dr. McMillin's expert report states that "[t]he probable causes of loss of bone structure and support leading to fatigue cracking and eventual failure of the femoral component are stress shielding of the underlying bone by the implant coupled with osteolysis."[33] Dr. McMillin also testified that "there's nothing wrong or defective about the Wright knee implant to the extent Mr. Kendrick had resulting osteolysis."[34] Dr. McMillin agreed that "the fact that a medical device fails is not indicative that it was defective."[35]

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[27] Ex. B to Mooney Decl. (Doc. 31) at 86.

[28] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 14; Ex. C to Mooney Decl. (Doc. 31) at 89; Ex. D to Mooney Decl. (Doc. 31) at 121.

[29] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 14.

[30] *Id.*

[31] Ex. J to Mooney Decl. (Doc. 31) at 200.

[32] *Id.*

[33] Ex. H to Mooney Decl. (Doc 31) at 163.

[34] Ex. J to Mooney Decl. (Doc 31) at 199.

[35] *Id.* at 194.

The parties agree that osteolysis caused the femoral component to undergo a fatigue fracture.[36] Osteolysis is a phenomenon that "causes 'empty spaces' or 'voids' at the bone-implant interface . . . ."[37] Dr. Edwards opines that "poor cement penetration/interdigitation in the cancellous bone along the posterior femoral cuts and posterior condyles of the total knee implant led to early loosening/failure of the implants."[38] Dr. Edwards also states that poor cement penetration caused the cement around Mr. Kendrick's implant to crack, which led to the accumulation of cement debris in and around Mr. Kendrick's implant.[39] The cement debris, in turn, "caused a massive amount of polyethylene wear and subsequent massive osteolysis with significant resorption of the bone around the posterior condyles of the implant."[40] Finally, the "[f]atigue fracture [of the Knee System] occurred along the femoral implant condyles as a result of the unsupported implant."[41] Mr. Kendrick has not presented any evidence refuting Dr. Edwards' explanation for the loss of bone support beneath the Knee System. And, as mentioned above, the parties agree that the loss of bone support caused the femoral component to fail.

Wright included "Instructions for Use" ("IFU") in the subject Knee System packaging.[42] Neither Wright nor Dr. Ball provided the IFU to Mr. Kendrick.[43] The IFU "contained warnings to the implanting physicians and were in effect as of the date of Mr. Kendrick's . . . surgery."[44]

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[36] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 14; Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37) at 3.

[37] Ex. D to Mooney Decl. (Doc 31) at 130.

[38] *Id.*; *see also* Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37) at 3.

[39] Ex. D to Mooney Decl. (Doc 31) at 130.

[40] *Id.* Dr. Ball explains that "when the bone reabsorbs, particularly in regard to an implant, if it reabsorbs from the surface of the implant, then that means that the implant will become loose." Ex. I to Mooney Decl. (Doc. 31) at 167.

[41] Ex. D to Mooney Decl. (Doc 31) at 130.

[42] Pls.' Resp. to Statement of Facts (Doc 38) ¶ 10; *see also* Ex. E to Mooney Decl. (Doc. 31) at 148.

[43] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 10.

[44] *Id.*

Specifically, the IFU warned of the risks of osteolysis and component fracture.[45] The IFU warned of the possibility of "[p]articulate generation leading to increased wear rates necessitating early revision . . . ."[46] The IFU also contained post-operative precautions, including the following:

> The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excess activity and trauma affecting the joint replacement have been implicated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.[47]

Dr. Ball indicates that he has never read the IFU.[48] However, Dr. McMillin (Plaintiffs' expert), Dr. Edwards (Wright's expert), and Dr. Ball all indicate that osteolysis is a risk generally known to orthopedists.[49]

A Wright representative attended Mr. Kendrick's initial surgery.[50] That representative never pointed out the IFU to Dr. Ball, nor did the representative verbally convey any risks to Dr. Ball.[51] Dr. Ball "placed no restrictions or limitations on Mr. Kendrick's activities."[52]

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[45] Ex. E to Mooney Decl. (Doc. 31) at 148–49.

[46] Pls.' Resp. to Statement of Facts (Doc. 38) ¶ 10.

[47] Ex. I to Mooney Decl. (Doc. 31) at 148; Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37) at 5. Wright presents expert testimony contending that Wright's warnings complied with FDA regulations and were otherwise adequate. Ex. B to Mooney Decl. (Doc. 31) at 60; Ex. D to Mooney Decl. (Doc. 31) at 134. Dr. McMillin does not contest the adequacy of Wright's warnings. Ex. I to Mooney Decl. (Doc. 31) at 195.

[48] Ex. I to Mooney Decl. (Doc. 31) at 170.

[49] *See* Ex. J to Mooney Decl. (Doc.31) at 198 (admitting that "every orthopedist knows or should know" that osteolysis is a risk in every total knee replacement); Ex. D to Mooney Decl. (Doc 31) at 135 ("All of the risks described in the package insert are well known and well understood in the general orthopedic community."); Ex. I to Mooney Decl. (Doc. 31) at 167–68 (adopting the statement that Dr. Ball was aware of the risk of osteolysis associated with knee implants before Mr. Kendrick's 2011 surgery and admitting that the risk was generally known in the orthopedic community).

[50] Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37) at 4.

[51] *Id.* at 4–5.

[52] *Id.* at 5.

II. Discussion

A court shall grant summary judgment when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law.[53] The moving party has the burden to show that (1) there is an absence of a genuine dispute of material fact on at least one essential element of the nonmoving party's case and (2) the absence means that a rational juror could not possibly find for the nonmoving party on that essential element of the nonmoving party's case.[54] Conversely, if the nonmoving party can present specific facts by "affidavit, deposition, or otherwise, showing the existence of a genuine issue for trial," then summary judgment is not appropriate.[55] Importantly, "[t]he mere existence of a factual dispute is insufficient alone to bar summary judgment."[56] The dispute of fact must be both genuine and material to prevent summary judgment.[57] A genuine dispute of fact exists where a rational juror could decide the particular question of fact for either party.[58] A material dispute of fact exists where the juror's decision on the particular question of fact determines the outcome of a potentially dispositive issue under the substantive law.[59]

Strict Liability Claims

To recover in strict liability under Arkansas law, Mr. Kendrick must show that "(1) he has sustained damages; (2) that [Wright] was engaged in the business of manufacturing, . . . or distributing the product; (3) that the product was supplied by [Wright] in a defective condition

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[53] *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042 (8th Cir. 2011) (citing FED. R. CIV. P. 56).

[54] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986).

[55] *Grey v. City of Oak Grove, Mo.*, 396 F.3d 1031, 1034 (8th Cir. 2005).

[56] *Holloway v. Pigman*, 884 F.2d 365, 366 (8th Cir. 1989) (citation omitted).

[57] *Id.*

[58] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

[59] *Id.*

which rendered it unreasonably dangerous; and (4) that the defective condition was a proximate cause of [Mr. Kendrick's] damages."[60] "'Defective condition' means a condition of a product that renders it unsafe for reasonably foreseeable use and consumption."[61] Arkansas recognizes three distinct product defects: manufacturing defects, design defects, and inadequate warnings.[62]

1. Manufacturing or Design Defect

"Manufacturing defects involve a configuration of a product that deviates from the intended design, while design defects involve a design that is executed according to plan but produces unintended or unwanted results."[63] For purposes of this opinion, the Court assumes that Mr. Kendrick has presented or identified evidence from which a rational juror could conclude that he sustained damages and that Wright manufactured the subject Knee System. As a result, the Court turns to whether Mr. Kendrick presented or identified evidence from which a rational juror could conclude that the subject Knee System was defectively manufactured or designed.

It is undisputed that the Knee System failed. But, on its own, that doesn't get Mr. Kendrick over the summary judgment hill. The Arkansas Supreme Court has made clear that "neither the mere fact of an accident, nor the fact that a product was found in a defective condition after an accident, makes out a case that a product was defective."[64] Something more is necessary. For example, "facts tending to show that the defect existed before the accident may make out a

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[60] *West v. Searle & Co.*, 305 Ark. 33, 37, 806 S.W.2d 608, 610 (1991) (citing Ark. Code Ann. §§ 16-116-101–107). As the Court is sitting in diversity jurisdiction, Arkansas substantive law governs this case. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

[61] Ark. Code Ann. § 16-116-202.

[62] *Searle*, 305 Ark. at 37, 806 S.W.2d at 610.

[63] *Simpson v. Wright Medical Group, Inc.*, No. 5:17-cv-00062-KGB, 2018 WL 1570795, at *9 (citing *Linden v. CNH America, LLC*, 673 F.3d 829, 834 (8th Cir. 2012)).

[64] *Pilcher v. Suttle Equip. Co.*, 365 Ark. 1, 7, 223 S.W.3d 789, 794 (Ark. 2006).

sufficient case."[65] Alternatively, without "direct proof of a specific defect, it is sufficient if a plaintiff negates other possible causes of failure of the product not attributable to the defendant."[66]

Mr. Kendrick has not presented or identified direct proof of a manufacturing defect. Indeed, Mr. Kendrick has not even suggested a specific manufacturing defect. On the other hand, Wright has submitted expert testimony showing that the explanted Knee System conformed to the Knee System's design specifications.[67] And Mr. Kendrick's sole expert, Dr. McMillin, testified that he knows of nothing to indicate that the subject Knee System departed from design specifications.[68]

Mr. Kendrick has not presented or identified direct proof of a design defect. That is not surprising, given the Knee System at issue appears to have failed only twice in ten years, equating to a known failure rate of 0.003%. Doctors McMillin and Edwards agree that the subject Knee System was not defectively designed. Indeed, nowhere in the briefing or record evidence does Mr. Kendrick or his expert even suggest what the design defect might be.[69]

Mr. Kendrick all but conceded the foregoing at the motion hearing.[70] That leaves him to rely on a *res-ipsa-loquitur*-type argument. But such an argument only works if Mr. Kendrick offers or points to record evidence that "negates other possible causes of the failure of the product not attributable to [Wright]."[71] He does not do so.

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[65] *Id.*

[66] *Id.*

[67] Ex. B to Mooney Decl. (Doc. 31) at 75.

[68] Ex. J to Mooney Decl. (Doc. 31) at 200.

[69] At the motion hearing, Mr. Kendrick's counsel speculated about some potential design defects. April 7, 2021 Hr'g Tr. at 39. For instance, Mr. Kendrick's counsel suggested that perhaps the metal on the device should have been thicker. *Id.* But none of his suggestions appear in or are supported by any record evidence or expert report.

[70] April 7, 2021 Hr'g Tr. at 44–48.

[71] *Madden v. Mercedes-Benz USA, Inc.*, 2016 Ark. App. 45, at 5, 481 S.W.3d 455, 459 (quoting *Higgins v. Gen. Motors Corp.*, 287 Ark. 390, 392, 699 S.W.2d 741, 743 (Ark. 1985)). Mr. Kendrick relies a great deal on Arkansas Model Jury Instruction 1016. But the permissible inference discussed therein only applies where "in the normal

It is undisputed that osteolysis resulted in bone resorption, which left the femoral component unsupported. Also undisputed is the fact that this lack of support caused the femoral component to fail. So, what caused Mr. Kendrick's osteolysis? Wright's orthopedic expert asserts that poor cement penetration into Mr. Kendrick's bone around the implant generated cement debris. This debris, according to that expert, created polyethylene particles that led to osteolysis.[72] Mr. Kendrick has not provided or identified any evidence that could negate this possible cause. Instead, confronted with these facts, Mr. Kendrick argues, without citation to the record, that a rational juror "could reasonably infer from the evidence of record that a knee implant which effectively destroys itself by generating small particles of polyethylene, metal, or cement, is a defective condition which renders the product 'unreasonably dangerous.'"[73] But there is no record evidence (in addition to no expert opinion) to lead a rational juror to conclude that the Knee System "destroy[ed] itself" and set off the speculative chain of events Mr. Kendrick suggests. Mr. Kendrick simply speculates that, because the femoral component failed, there must have been a defect. Such speculation falls far short of dispelling other causes not attributable to Wright. No rational juror could conclude otherwise. The Court therefore grants summary judgment to Wright on Mr. Kendrick's design and manufacturing defect claims.[74]

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course of events no (injury) . . . would have occurred without some defect." AMI 1016. That's essentially the "negates" test.

[72] *Supra* notes 38, 39, 40.

[73] Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37) at 4.

[74] Because the Court determines that no rational juror could conclude that the Knee System was defective, the Court does not have to address whether the Knee System was unreasonably dangerous. Additionally, the parties have not raised this issue. But even if the Court reached that question, it would conclude that no rational juror could find that the Knee System was unreasonably dangerous. "For a product to be unreasonably dangerous under Arkansas law, the product failure must be an occurrence that the reasonable buyer or user did not contemplate, taking into account any special knowledge of the buyer." *Kaplon v. Howmedica, Inc.*, 83 F.3d 263, 267 (8th Cir. 1994) (citing *Purina Mills, Inc. v. Askins*, 317 Ark. 58, 66, 875 S.W.2d 843, 847 (1994) and *Berkeley Pump Co. v. Reed–Joseph Land Co.*, 279 Ark. 384, 394, 653 S.W.2d 128, 132–33 (1983)). Dr. Ball testified that he told Mr. Kendrick "that there are early failures and that statistically . . . the failure rate is low." Ex. 4 to Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37-4) at 160:3–5. Dr. Ball also agreed with Mr. Kendrick's counsel that "the expectation is that the implant would not be subject to breakage unless it was unsupported." *Id.* at 136:1–13. This

2. Warning Defect

Mr. Kendrick's defective warning claim cannot survive summary judgment either. As a general rule, a manufacturer has a duty to warn the ultimate user of the risks of its product."[75] But this general rule is not without important exceptions. For example, in a case involving prescription drug products, the Arkansas Supreme Court held that the learned intermediary doctrine is an exception to this general rule.[76] Under that doctrine, "a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug."[77]

The application of the learned intermediary rule to the case at bar is hotly contested. Wright argues that this doctrine is just as applicable to medical devices and cites non-binding cases for that proposition.[78] Mr. Kendrick disagrees, and argues that the cases are either distinguishable or not persuasive. Sitting in diversity jurisdiction, the Court must predict whether the Arkansas Supreme Court would extend this doctrine to a prescription medical device.[79] The Court concludes that the Arkansas Supreme Court would do so.

The Arkansas Supreme Court's reasoning in *West v. Searle & Company* applies with equal force here. In *Searle*, the Arkansas Supreme Court emphasized the overarching reason for the application of the learned intermediary doctrine, namely, the existence of "an independent medical

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testimony shows that Dr. Ball did in fact contemplate the failure that occurred here. In *Kaplon*, the Eighth Circuit came to a similar conclusion. 83 F.3d at 267. There, the evidence showed that a plaintiff's doctor had seen a medical device fail before that same device failed while inside the plaintiff. *Id.* The plaintiff argued that the doctor did not contemplate the device failing as quickly as it did. *Id.* The doctor did say that he did not anticipate the speed with which the device failed. *Id.* The doctor also testified, however, that "the orthopedic community refers to the implant process as a race between implant failure and bone healing. *Id.* The Eighth Circuit did "not believe that a jury could find from this evidence that [the doctor] did not contemplate that the [device] might break within seven months under some circumstances, and thus a jury could not find that the [device] was unreasonably dangerous." *Id.*

[75] *Searle*, 305 Ark. at 42, 806 S.W.2d at 613.

[76] *Id.*, 806 S.W.2d at 613.

[77] *Id.*, 806 S.W.2d at 613.

[78] Br. in Supp. of Def.'s Mot. for Summ. J. (Doc. 29) at 26.

[79] *Williamson v. Hartford Life and Acc. Ins. Co.*, 716 F.3d 1151, 1154 (8th Cir. 2013).

decision by the learned intermediary."[80] The court also presented three public policy reasons for the application of the doctrine: (1) "a physician must prescribe the drug, the patient relies on the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug;" (2) "it is virtually impossible in many cases for a manufacturer to directly warn each patient;" and (3) "imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient."[81] These reasons convinced the court that the doctrine was appropriate with respect to prescription drugs.[82]

The same reasons apply here. First, the Knee System is a prescription device. As the record shows, Dr. Ball selected the Knee System for Mr. Kendrick's surgery.[83] This selection constitutes "an independent medical decision by the learned intermediary" that the Knee System was appropriate.[84] Also, Mr. Kendrick relied on that selection. Or, at least, the record does not show that Mr. Kendrick requested the specific Knee System. Second, this isn't a situation where a person goes to a dealership to select a vehicle; Wright does not know ahead of time who the end consumer will be. This means that it would be difficult, if not "virtually impossible," for Wright to have warned Mr. Kendrick prior to his surgery.[85] And third, imposing such a duty to warn on Wright would "interfere with the relationship between [Dr. Ball] and [Mr. Kendrick]."[86]

Because the Arkansas Supreme Court would apply the learned intermediary doctrine to the facts of this case, Mr. Kendrick's defective warning claim turns (at least in part) on whether Wright

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[80] *Searle*, 305 Ark. at 42, 806 S.W.2d at 613.

[81] *Id.* at 42, 806 S.W.2d at 613.

[82] *Id.* at 44., 806 S.W.2d at 614.

[83] Ex. 4 to Pls.' Br. in Opp'n to Def.'s Mot. for Summ. J. (Doc. 37-4) at 184:1–19.

[84] *Searle*, 305 Ark. at 42, 806 S.W.2d at 613.

[85] *Id.*, 806 S.W.2d at 613.

[86] *Id.*

provided adequate warnings to Dr. Ball.[87] Under Arkansas law, Wright had a duty to provide an adequate warning regarding the risks of the Knee System to Dr. Ball.[88]

As set forth in the Background section, the IFU listed component fracture, particulate generation, and osteolysis as adverse effects. The IFU was available to Dr. Ball; it came in the Knee System packaging. Wright's experts opine that Wright's IFU complied with FDA regulations and were adequate to warn of the attendant risks of the Knee System. Dr. McMillin (Mr. Kendrick's expert) does not opine on the adequacy of the warnings. The learned intermediary, Dr. Ball, testified that he did not read the IFU but that he was still aware of the aforementioned risks before Mr. Kendrick's first surgery. On the record, then, Wright proffers evidence that the risks that manifested in Mr. Kendrick's case were warned of in the IFU. That Dr. Ball did not read the warnings is of no account[89] because he knew of these risks and made the medical decision not to pass that information along to Mr. Kendrick. The Court concludes that Wright's warnings to Dr. Ball were adequate. No rational juror could conclude otherwise. The Court therefore grants summary judgment to Wright on Mr. Kendrick's defective warnings claim.

Even if Mr. Kendrick could somehow establish that Wright's warnings were inadequate, the Court would still grant summary judgment on this claim because Mr. Kendrick cannot, on this record, establish proximate cause—a necessary element of any strict liability claim. The Eighth Circuit, applying Arkansas law, states that "[a] manufacturer's inadequate warning is not a proximate cause of a plaintiff's harm so long as the prescribing physician had independent

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[87] *See id.* at 44, 806 S.W.2d at 615 (reversing summary judgment in favor of pharmaceutical company because the warnings the "learned intermediary" relied upon were not properly in the record, which meant the trial court did not have any evidence regarding the adequacy of the warnings).

[88] *See Boehm v. Eli Lilly & Co.*, 747 F.3d 501, 503 n.2 (8th Cir.2014) (explaining Arkansas's learned intermediary rule).

[89] To the extent it is of any relevance, it creates causation problems for Mr. Kendrick. If Dr. Ball did not read the IFU warnings, then Wright's alleged omission of a warning could not be the cause of the use of the Knee System.

knowledge of the risk that the inadequate warning should have communicated."[90] As discussed above, Dr. Ball testified that he never read the IFU and yet was still aware of all of the risks that Mr. Kendrick ultimately experienced. Additionally, Mr. Kendrick has not come forward with any additional risks that Dr. Ball should have been made aware of that would have led Dr. Ball or Mr. Kendrick to decide against the surgery or the use of the Knee System.[91] That being the case, a rational juror could not find (on this record) that any inadequate warnings on Wright's part could have proximately caused Mr. Kendrick's injuries.

Implied Warranty Claims

Mr. Kendrick cannot survive summary judgment on his breach-of-warranty claims. In *Higgins v. General Motors Corporation*, the Arkansas Supreme Court analyzed a plaintiff's breach-of-warranty claim under a strict-liability framework.[92] Specifically, the court noted that breach-of-warranty claims and strict-liability claims require proof that "a defect in the product existed" and "that such defect was the proximate cause of the injury."[93] In short, the Arkansas Supreme Court holds that a plaintiff must establish "essentially the same" elements to prevail on a strict liability claim and a breach-of-warranty claim.[94] Because the Court has already concluded that Mr. Kendrick has not presented or identified any evidence that could lead a rational juror to conclude that a defect existed, Mr. Kendrick's breach-of-warranty claims don't survive summary judgment.

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[90] *Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013).

[91] At Mr. Kendrick's deposition, Wright's counsel asked Mr. Kendrick, "[a]re there any warnings regarding risks associated with the Wright implant that you contend that Wright Medical should have told Dr. Ball but that Wright Medical did not." Ex. K to Mooney Decl. (Doc. 31) at 207. Mr. Kendrick responded, "[n]o sir." *Id.*

[92] 287 Ark. at 391, 699 S.W.2d at 743.

[93] *Id.*

[94] *Id.*

Negligence Claims

Mr. Kendrick alleges that Wright was negligent by "failing to properly inspect and test the artificial knee components for defects prior to supplying the product for implantation into the body of Billy Ray Kendrick."[95] To establish negligence under Arkansas law, "the plaintiff must prove that the defendant owed a duty to the plaintiff, that the defendant breached that duty, and that the breach was the proximate cause of the plaintiff's injuries."[96]

There's no record evidence from which a rational juror could find negligence. For starters, Wright has provided an expert report showing that Wright had a "well-functioning Quality System," and that it used "appropriate methods to evaluate the safety and effectiveness of the device."[97] Wright's expert also opined that Wright complied with FDA regulations as they relate to medical device manufacturers.[98] Additionally, Wright has also submitted expert testimony that the manufacture and design of the subject Knee System were not defective. On the other hand, Mr. Kendrick has presented one expert who largely agrees with Wright's experts, or at least he does not genuinely contest their opinions. Mr. Kendrick has put on no other expert testimony or direct proof that Wright failed to conduct itself as a prudent company would have conducted itself. In short, Mr. Kendrick has not raised a triable fact with respect to his negligence claims. No rational juror could find negligence on this evidentiary record. Just as Mr. Kendrick cannot rely solely on the femoral component's failure to sustain his strict liability claims, he cannot rely solely on that failure to establish negligence. It is black letter law in Arkansas that "[t]he mere fact of an

[95] Pls.' Compl. (Doc. 2) ¶ 14.

[96] *Yanmar Co., Ltd. v. Slater*, 2012 Ark. 36, at 16, 386 S.W.3d 439, 449.

[97] Ex. C to Mooney Decl. (Doc. 31) at 118.

[98] *Id.*

accident does not give rise to an inference of negligence."[99] The Court therefore grants summary judgment to Wright on Mr. Kendrick's negligence claims.

III. Conclusion

Defendant's Motion for Summary Judgment is GRANTED in its entirety.[100]

IT IS SO ORDERED this 10th day of August 2021.

LEE P. RUDOFSKY
UNITED STATES DISTRICT JUDGE

[99] *Yanmar*, 2012 Ark. 36, at 16, 386 S.W.3d 439, 449.

[100] The Court notes that Mr. Kendrick sued John Does 1–5 in addition to Wright. Mr. Kendrick has never named any additional defendants. The Court therefore dismisses without prejudice Mr. Kendrick's claims against the fictitious parties. *See Estate of Rosenberg by Rosenberg v. Crandell*, 56 F.3d 35, 37–38 (affirming the dismissal of "various John Does" because the complaint did not make "allegations specific enough to permit the identity of the part[ies] to be ascertained after reasonable discovery"). Ms. Kendrick's claim is dismissed with prejudice. *See supra* note 2 (highlighting the fact that Ms. Kendrick's claim is entirely derivative of Mr. Kendrick's claims).